DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1277]

Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds." The purpose of this guidance is to identify for the industry fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. The agency is also announcing the availability of the final supporting documents entitled "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," and "Background Paper in Support of Fumonisin Levels in Animal Feed."

DATES: Submit written or electronic comments concerning the final guidance and the final supporting documents at any time.

ADDRESSES: Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for single copies of the final guidance entitled "Guidance for Industry: Fumonisin Level in Human

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Foods and Animal Feeds" to Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN) (address below), or Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT:

Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631, or

Randall Lovell, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0176.

SUPPLEMENTARY INFORMATION:

I. Background

On June 6, 2000, FDA issued a draft guidance document that presented recommended levels of fumonisins in corn used for production of human foods and animal feeds. The purpose of the draft guidance was to identify for the industry fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. In the **Federal Register** notice of June 6, 2000 (65 FR 35945) announcing the availability of the draft guidance document, FDA provided a 60-day period for comment on the recommended fumonisin levels.

FDA received 12 comments in response to the June 6, 2000, draft guidance. The comments represented the views of seven trade associations representing manufacturers of dry and wet milled corn products, popcorn, snack foods, processed grain and feed products, food and other consumer products, and pet foods; a snack food company; a dry miller of corn; a food and food ingredient company; a State health department; and a life science society. The majority of the comments stated that they supported the recommended fumonisin levels in corn used for production of human foods and animal feeds. A number of comments suggested changes or modification to the various

recommended fumonisin levels. FDA has considered the submitted comments and has revised the supporting documents as appropriate.

II. Conclusion

The agency is adopting the recommended fumonisin levels in human foods and animal feeds as presented in the draft guidance document. The majority of the comments that the agency received supported the recommended fumonisin levels. Further, after considering carefully the comments that the agency received that suggested modification or opposition to aspects of the recommended levels in the draft guidance, the agency has determined that no changes are warranted. The final supporting documents explain the agency's reasoning in selecting the recommended levels.

FDA considers the final guidance to be a prudent public health measure during the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. Based on information obtained from future national and international workshops on the risk from exposure to fumonisins, FDA will consider whether to establish tolerances, regulatory limits, or action levels, as appropriate, for fumonisins in human foods and animal feeds, respectively, under 21 CFR part 109—Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material and under 21 CFR part 509—Unavoidable Contaminants in Animal Food and Food-Packaging Material.

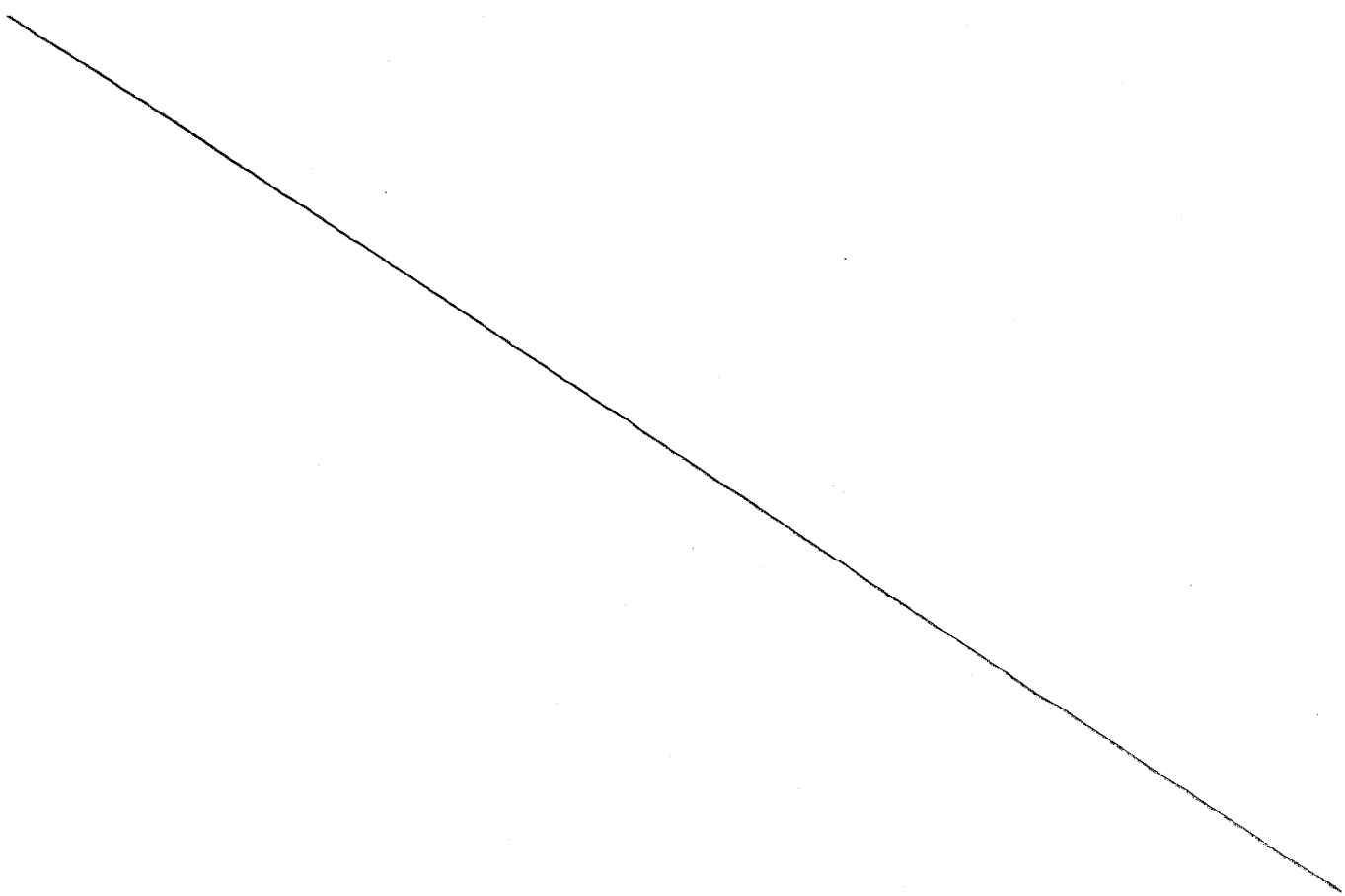
The final guidance document is being issued as a level 1 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The final guidance represents the agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the final guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The final guidance, the final supporting documents entitled "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," and "Background Paper in Support of Fumonisin Levels in Animal Feed," and received comments are available in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

IV. Electronic Access

The final guidance, as well as the final supporting documents entitled "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," and "Background Paper in Support of Fumonisin Levels in Animal Feed," may be accessed from



the home pages of CFSAN and CVM on the Internet at http://www.cfsan.fda.gov and http://www.fda.gov/cvm, respectively.

Dated: 11/1/01
November 1, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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